



UNITED STATES PATENT AND TRADEMARK OFFICE

cy
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------------------------------------|-------------|----------------------|-----------------------------|------------------------|
| 10/788,663 | 02/27/2004 | Rainer Gruening | 136-36 | 3625 |
| 23869 | 7590 | 07/10/2007 | | |
| HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791 | | | EXAMINER CHONG, YONG SOO | |
| | | | ART UNIT 1617 | PAPER NUMBER |
| | | | MAIL DATE 07/10/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|----------------------------------------|--|
| Office Action Summary | Application No. 10/788,663 | Applicant(s) GRUENING ET AL. | |
| | Examiner Yong S. Chong | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-32 and 34-51 is/are pending in the application.
- 4a) Of the above claim(s) 37, 39 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-32, 34-36, 38, 41-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 6/1/2007.

Claim(s) 1-23, 33 have been cancelled. Claim(s) 51 has been added. Claim(s) 24-32, 34-51 are pending. Claim(s) 24, 30-31 have been amended. Claim(s) 37, 39-40 have been withdrawn. Claim(s) 24-32, 34-36, 38, 41-51 are examined herein.

Applicant's amendments have rendered the provisional double patenting rejection under 35 U.S.C. 101 over copending Application No. 11/416,060 moot, therefore hereby withdrawn.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified below for Applicant's convenience. The following new rejection will also apply.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1617

Claims 24-32, 34-36, 38, 41-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 11/416,060. Although the conflicting claims are not identical, they are not patentably distinct from each other because a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, spermicide, and glutaraldehyde is disclosed for the purpose of inhibiting the intrusion of micro-organisms into a body cavity in the preamble.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's request to file a terminal disclaimer once the instant application is allowed, is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 24-32, 34-36, 38, 41-50 are rejected under 35 U.S.C. 103(a) as being obvious over Beckman et al. (US Patent Application 2002/0015697 A1).

The instant claims are directed to a method of inhibiting the intrusion of microorganisms into a body cavity of a mammal comprising applying into the body cavity a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, and glutaraldehyde.

Beckman et al. teach methods, compositions, and kits for reducing a microbial population on a surface (abstract), such as the epidermal skin, mucosal surface, a wound, an abrasion, a burn, or a damaged region of tissue (section 0009). Other medical applications include the skin of a patient, teat of a dairy cow, oral cavity, vaginal cavity, and other living tissues of human beings (section 0078). The composition comprises transition metals prepared in water (section 0043), iodine, glutaraldehyde (section 0049), polyurethanes (section 0051), chitosan (section 0052), polyvinylpyrrolidone (section 0145), parabens (section 0149), water, alcohol, and dyes (section 0155). The antimicrobial compositions can be applied with a sponge, a mop, a

Art Unit: 1617

cloth, or any other of a variety of techniques known to one of skill in the art of disinfection (section 0055).

It is obvious for one of ordinary skill in the art to use O-carboxymethyl chitosan and ethyl or isopropyl alcohol since the genus chitosan and alcohols were disclosed in the prior art. Examiner notes that this is a typical genus/species situation. Once a *prima facie* case of obviousness is established, the burden is shifted to the Applicant for objective evidence for nonobviousness. See MPEP 2144.08.

However, Beckman et al. fail to disclose a single example of a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, and glutaraldehyde.

It would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to formulate a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, and glutaraldehyde for the method of inhibiting the intrusion of microorganisms into a body cavity.

A person of ordinary skill in the art would have been motivated to formulate a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, and glutaraldehyde because of the reasonable expectancy of success in inhibiting the intrusion of microorganisms into a body cavity.

Claim(s) 51 is rejected under 35 U.S.C. 103(a) as being obvious over Beckman et al. (US Patent Application 2002/0015697 A1) as applied to claims 24-32, 34-36, 38, 41-50 in view of Stoner (US Patent 4,925,033).

The instant claims are directed to a method of inhibiting the intrusion of microorganisms into a body cavity of a mammal comprising applying into the body cavity a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, spermicide, and glutaraldehyde.

Beckman et al. teach as disclosed above, however, do not teach spermicide in the composition.

Stoner teaches that a microbicidal cleanser composition to be used during sexual contact (abstract) so as to prevent the transmission of sexually transmitted diseases. This composition may also be in the form of contraceptives, such as coating fluids (foams, creams, jellies) to be used on the genitals. A well-known composition of the above type is nonoxynol-9, a spermicidal compound that also acts as an anti-microbial agent (col. 1, lines 19-58).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to combine the antimicrobial composition disclosed by Beckman et al. with the spermicidal composition disclosed by Stoner.

A person of ordinary skill in the art would have been motivated to combine the antimicrobial composition disclosed by Beckman et al. with the spermicidal composition disclosed by Stoner because: (1) both compositions are disclosed to possess

Art Unit: 1617

antimicrobial properties; (2) both compositions are to be used on the genitals, such as the vaginal cavity; (3) Stoner discloses that antimicrobial compositions comprising spermicides are used to prevent sexually transmitted diseases; and (4) Stoner discloses nonoxynol-9, a well-known spermicidal compound that also acts as an anti-microbial agent. Therefore, the skilled artisan would have had a reasonable expectation of success in preventing STDs by administering a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, spermicide, and glutaraldehyde.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Response to Arguments

Applicant argues that Beckman does not teach hydrogels because water in any amount is not among the components disclosed. This is found not persuasive because Beckman's compositions can be in the form of gels (section 0058). Water is a preferred component in the compositions taught by Beckman since it is disclosed in the oral rinse composition (section 0155). Therefore, it is obvious to use water in any composition disclosed by Beckman, especially since gel formulations are taught.

Applicant also argue that the relative amount of a poly(N-vinyl) lactam to polysaccharide is not taught by the cited prior art.

Generally, mere optimization of ranges will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimal or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *In re Peterson*, 315 F. 3d at 1330, 65 USPQ 2d at 1382 "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." MPEP 2114.04.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1617

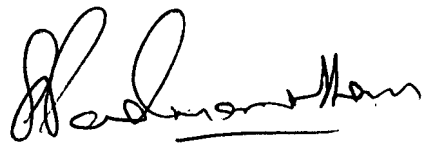
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER